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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/017,715	02/03/98	Ji	H 1488.0810003

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HM22/1023

EXAMINER

CANELLA, K

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/017,715

Applicant(s)

Ji et al

Examiner

Karen Canella

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12, 14-47, 50, 51, 53, and 57-79 is/are pending in the application.
- 4a) Of the above, claim(s) 10-12, 14, 15, and 79 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-47, 50, 51, 53, 57-70, and 78 is/are allowed.
- 6) ☒ Claim(s) 71-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: Petition Decision

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 48, 49, 52 and 54-56 have been canceled. Claims 10-12, 14-47, 50, 51, 53 and 57-79 are under pending. Claims 10-12, 14, 15 and 79, drawn to non-elected inventions, remain withdrawn from consideration. Claims 16-47, 50, 51, 53 and 57-78 are under consideration.

Claim Rejections Maintained

3. The rejection of claims 71-77 under 35 U.S.C. 112, first paragraph is maintained for reasons of record. Claims 71-77 are drawn to polynucleotides comprising nucleic acids 95% or more identical to nucleic acids encoding SEQ ID NO:2, polynucleotides encoding an amino acids sequence having one to thirty conservative amino acid substitutions in SEQ ID NO:2, isolated polynucleotides comprising nucleic acids which encode for an amino acids sequence 95% or more identical to SEQ ID NO:2, polynucleotides comprising nucleic acids which encode for an amino acids sequence 95% or more identical to or the amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97856, polynucleotides having 95% or more identity over the full length of a portion of SEQ ID NO:1, said portion defined by nucleotides 15-392 of SEQ ID NO:1 and nucleotides 12-392 of SEQ ID NO:1. Applicant argues that these variant polynucleotides would be useful for the detection of the reference polynucleotide, and therefore the specification is enabling for the claimed polynucleotide variants. Applicant further asserts that polypeptides which are 95% identical to the claimed SEQ ID NO:1 are not taught by the specification to be overexpressed in breast cancer. This has been considered but not found persuasive, as one of skill in the art would not use a variant of SEQ ID NO:1 in a hybridization method for detecting SEQ ID NO:1 as indicative of stage-specific breast cancer as the hybridization would preferentially detect the variant of SEQ ID NO:1, not SEQ ID NO:1. Applicant further argues that the variant polypeptides encoded by the variant polynucleotides could be used to generate antibodies that bind to the polypeptide of SEQ ID NO:2. This has been


considered, but not found persuasive as one of skill in the art would not use a variant polypeptide to generate antibodies that would bind to SEQ ID NO:2, as the variant polypeptide would contain epitopes that would produce antibodies which did not bind SEQ ID NO:2.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1100

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
October 18, 2001